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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 10/005,699 12/07/2001 T. Anthony Don Michael DON MICHAEL=27 7636 1444 10/19/2004 **EXAMINER** 7590 HO, UYEN T BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW PAPER NUMBER ART UNIT SUITE 300

3731
DATE MAILED: 10/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

			Application No.	Applicant(s)		
Office Action Summary			10/005,699	DON MICHAEL, 1	T. ANTHONY	
		Examiner	Art Unit			
			(Jackie) Tan-Uyen T. Ho	3731		
The Period for Rep	MAILING DATE of this commun.ly	ication appe	ars on the cover sheet with t	the correspondence ad	ldress	
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)⊠ Respo	onsive to communication(s) file	d on <u>19 <i>Jul</i>y</u>	<u>/ 2004</u> .			
2a)⊠ This a	action is FINAL.	2b)⊟ This a	ction is non-final.		į	
·	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4a) Of 5)	4) ☐ Claim(s) 1-10 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  5) ☐ Claim(s) is/are allowed.  6) ☐ Claim(s) 1-10 is/are rejected.  7) ☐ Claim(s) is/are objected to.  8) ☐ Claim(s) are subject to restriction and/or election requirement.					
Application Pa	pers					
9)∏ The sp	pecification is objected to by the	e Examiner.			•	
10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.						
	Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority under	35 U.S.C. § 119				•	
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
Attachment(s)						
2) Notice of Dra 3) Information D	rerences Cited (PTO-892) Iftsperson's Patent Drawing Review (P Disclosure Statement(s) (PTO-1449 or Mail Date			mary (PTO-413) lail Date mal Patent Application (PTG	O-152)	

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### **DETAILED ACTION**

### Response to Arguments

Applicant's arguments filed 7/19/2004 have been fully considered but they are 1. not persuasive. The functional limitations "high compliance" and "low compliance" do not impose any structural limitations on the claims distinguishable over the Nap et al. in Since each balloon of Nap et al. is inherently higher view of Sahota's device. compliance than a certain balloon in the art and lower compliance than a certain balloon in the art. The broadest reasonable interpretation of "high compliance" balloon or "low compliance" balloon encompasses a balloon being made from any material that is not a highest or lowest compliance material. Any angioplasty balloon or occluding balloon in the art is inherently being made from a material that is not the highest or lowest compliance material. Therefore, each balloon of Nap et al. is inherently higher compliance than a certain balloon to meet claimed limitation "high compliance blocking balloon" and lower compliance than a certain balloon to meet claimed limitation "low compliance angioplasty balloon." Furthermore, the present application does not discloses a material of high or low compliance to make it different from the balloon of Nap et al. or other balloon.

# Claim Rejections - 35 USC § 103

- 2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nap et al. (5,971,955) in view of Sahota (5,160,321). Nap et al. disclose a balloon catheter for treating stenotic regions including all the limitations of the claims except for a presence of inlet and outlet openings. Sahota disclose a balloon catheter for treating stenotic regions including inlet and outlet openings (figure 8) allow blood to perfuse through and bypass the dilation balloon so as to maintain blood flow during treatment. Therefore, it would have been obvious to one having ordinary skill in the time the invention was made to employ inlet and outlet openings as disclose by Sahota into Nap et al.'s catheter in order to allow blood to perfuse through and bypass the dilation balloon so as to maintain blood flow during treatment.

#### Conclusion

- 4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Stack et al. (6,165,196) disclose a perfusion occlusion apparatus. Kohish et al. disclose angioplasty/blockage balloon being made from low or high compliance material.
- 5. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is

(703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, ANHTUAN or NGUYEN can be reached on 703-308-2154. The fax phone

number for the organization where this application or proceeding is assigned is 703-

872-9306.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

(Jackie) Tan-Uyen T. Ho

Patent Examiner

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October 7, 2004

ANHTUAN T. NGUYEN PRIMARY EXAMINER

10/14/04